REMARKS

I. Status of the Claims

Claims 1-18 are pending in the application. In response to the restriction requirement, applicant elected, with traverse, to prosecute claim 18, the Group II claim. Thus, claims 1-17 are withdrawn, and claim 18 is under consideration and stand rejected under 35 U.S.C. §112, first and second paragraphs and 35 U.S.C. §103. The specific grounds for rejection, and applicant's response thereto, are set out in detail below.

II. Objections

Claim 18 is objected to for alleged grammatical informalities. Amendments have been provided. Reconsideration and withdrawal of the objections is therefore respectfully requested.

III. Rejections under 35 U.S.C. §112

A. Second Paragraph

Claim 18 is rejected for alleged indefiniteness. The term to which the examiner objects has been removed by amendment. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

B. First Paragraph

Claim 18 stand rejected as allegedly lacking enablement. The only basis for the rejection is that there are no working examples in the application to demonstrate the physiologic effect of administering the disclosed compositions. No attempt is made to argue that if one were to follow the teachings of the specification, and the physiologic effect were bona fide, that enablement

would not exist. Thus, the entire boils down to one of whether or not applicant's methods actually work. As explained below, they do indeed, and therefore the rejection is traversed.

As well documented, ethanol is first metabolized to acetaldehyde by alcohol dehydrogenase (ADH), and then acetaldehyde is further metabolized to acetic acid by aldehyde dehydrogenase (ALDH), mainly by liver aldehyde dehydrogenase 2 (ALDH2). Acetic acid is immediately converted to acetyl-CoA, which is then metabolized to carbon dioxide and water in the citric acid cycle (Krebs cycle, tricarboxylic acid cycle, TCA cycle) or used as the immediate substrate for fatty acid biosynthesis.

Appended to this response is a declaration outlining and experiment performed to demonstrate the efficacy of the claimed invention. In this experiment, a supplement was orally administered to five subjects prior to drinking alcohol. Then, each subject drank 400 ml of wine within 30 minutes. Thirty minutes after ingesting the wine, blood was taken from the subjects and the concentration of ethanol and acetaldehyde in the blood of the subjects was determined. For the control five subjects, they also drank the same kind and amount of wine, but no supplement was administrated prior to drinking. The values of the ethanol and acetaldehyde blood concentration of the subjects to whom the supplement was administrated compared with the values of the ethanol and acetaldehyde blood concentration in the controls is illustrated in Fig.1. The result of this experiment clearly shows that both the ethanol and acetaldehyde concentration in the blood of the subjects was decreased as compared to that of the controls, and thus provides evidence that the composition as described in the present application confers the claimed benefits.

The reduction of ethanol metabolism by slowing down the process of ethanol oxidation into acetaldehyde to prevent accumulation of acetaldehyde, the stimulation of the activity of

ALDH, as well as the speeding up of the reaction from acetaldehyde to acetic acid is shown by the reduction of the acetaldehyde concentration in the blood of the subjects. Therefore, it is believed that the rejection is overcome. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

IV. Rejection under 35 U.S.C. §103

Claim 18 is rejected by the examiner under 35 U.S.C. 103(a) as being unpatentable over Popp *et al.* (U.S. Patent 6,630,158) and Amselem (U.S. Patent 5,989,583). Applicants traverse.

The subject matter of claim 18 involves a method of affecting the alcohol degrading process in respect to ethanol metabolism within the human body comprising administering to a subject the food composition or dietary supplementation, wherein said method has the following effects within the human body: reducing ethanol metabolism by slowing down the process of ethanol oxidation into acetaldehyde to prevent accumulation of acetaldehyde in the first place (*i.e.*, the ethanol metabolism is reduced after the consumption of alcohol and prior to the formation of acetaldehyde); stimulating the activity of ALDH and avoiding any blockade of its enzymatic activity; speeding up the reaction from acetaldehyde to acetic acid and further decomposition in the citrate cycle; and improving the levels of those anti-oxidants of the alcohol consumer which specially protect against toxic effects of acetaldehyde. The administrated food composition or dietary supplementation comprises the following substances: dextrose, Vitamin C, L-glutamine, cysteine, riboflavin, succinic acid and/or fumaric acid and coenzyme Q10.

According to the examiner, Popp *et al.* teaches each element of the claimed composition but for succinic acid and fumaric acid. That is incorrect. Popp *et al.* discloses a dietary supplement composition for promoting and maintaining healthy skin containing essential

ingredients lycopene carotenoids, biotin, chromium and selenium (see Popp *et al.*, column 4, l. 6-9). In addition to these essential ingredients, the composition is said to optionally contain compounds such as: vitamin A, vitamin C, calcium, iron, vitamin D, vitamin E, vitamin K, thiamine, riboflavin, niacin, vitamin B6, folate, vitamin B12, biotin, pantothenic acid, phosphorus, iodine, magnesium, zinc, copper, manganese, molybdenum, chloride (see Popp *et al.*, column 7, l. 12-18). Compounds such as glucose among others are used as fillers or extenders (see Popp *et al.*, column 7, l. 64-65). The composition disclosed in Popp *et al.* does not, however, include L-glutamine, cysteine or coenzyme Q10, in addition to the succinic acid and/or fumaric acid discussed above. The only mention of L-glutamine, cysteine or coenzyme Q10 is in the background with reference to the prior art.

Thus, even to approach a composition lacking L-glutamine, cysteine, coenzyme Q10, succinic acid and fumaric acid, the skilled artisan would be forced to pick and choose among hundreds of thousands of different potential combinations as generically disclosed in Popp *et al.* There is no specific direction, nor even general guidance, that would direct the skilled person to create and use a composition according to the present invention, but lacking the five elements set out above. Thus, it is very unlikely that the person skilled in the art would ever get to the point of looking at an additional supporting reference to complete the deficiencies in Popp *et al.*

Moreover, the composition disclosed in Popp *et al.* is for promoting and maintaining healthy skin. Contrarily, the composition of the present invention is active in respect to the support and/or the moderation of an alcohol degradation process within the human body (see originally filed application, p. 1, first section). Thus, the two documents totally differ in their field. Therefore, a person skilled in the art would not recognize this reference as having relevance to the present invention given that it relates to a totally different field.

Even if one were to consider the relevance of the background art cited in Popp *et al.* for assessing obviousness, such would be unavailing. U.S. Patent 6,103,756 discloses oral compounds and methods for treating diseases of the eye comprising: vitamin A, vitamin E, vitamin C, magnesium, selenium, bilberry extract, L-taurine, lutein extract, lycopene extract, alpha lipoic acid, quecetin, rutin and citrus bioflavonoids. The formulation optionally contains at least one of the following: vitamin D3, thiamine, riboflavin, niacin, vitamin B6, folic acid, vitamin B12, biotin, pantothenic acid, calcium, iodine, zinc, copper, manganese, chromium, molybdenum, n-acetyl-cysteine, plant enzymes, biopene, malic acid, L-glycine, L-glutathionine or boron (see Popp et al., column 3, l. 46-56). Additionally, U.S. Patent 6,048,846, which discloses a dietary supplement comprising dehydroepiandrosterone (DHEA) or melatonin, an amino acid selected from the group consisting of tarine, arginine, tyrosine and glutamine, coenzyme Q10, and at least one mineral selected from the group consisting of calcium, magnesium, potassium, zinc and copper. Also disclosed are optionally including antioxidants selected from one or more of the group consisting of: multi-carotenes, alpha-, beta-, and gamma carotenes, lycopene, lutein, zeanthins, vitamin E, vitamin C and niacin (see Popp *et al.*, column 3, l. 57-66). These compositions may overlap with compounds of the composition of the present invention (*e.g.*, vitamin C and riboflavin; glutamine, coenzyme Q10 and vitamin C), but none of these documents disclose all ingredients of the composition of the present invention, or suggest the complex "picking and choosing" that would be required to arrive at the presently claimed invention.

As indicated above, Popp *et al.* does not disclose the either succinic acid or fumaric acid. For these elements, the examiner has referred to Amselem *et al.* Amselem *et al.* discloses dry solid lipid compositions for the oral delivery of lipophilic substances, and methods for preparing

and using such compositions. The lipid composition disclosed in Amselem et al. showed higher bioavailability of lipophilic substances, such as coenzyme Q10 by addition of antioxidants, such as α-tocopherol (*e.g.*, tocopherol succinate) which lessen the formation of oxidative degradation products from ***unsaturated lipids*** (Amselem *et al.*, col. 6, l. 62 to col. 7, l.1-2).

Consequently, Amselem *et al.* does not disclose succinic acid, but α-tocopherol and its derivatives. In this connection, one is not instructed to use succinic acid, but α-tocopherol. The succinate is in this regard only the form in which the α-tocopherol (as the effective antioxidant) is provided. Thus, the skilled person would derive no suggestion from Amselem *et al.* to use succinic acid.

Moreover, Amselem *et al.* does not teach use of α-tocopherol succinate in combination with coenzyme Q10 to lessen oxidation of the coenzyme Q10, as indicated by the examiner, because coenzyme Q10 is a lipophilic substance (see Amselem *et al.*, col. 2, l. 59-61), and is not an unsaturated lipid. Yet, as discussed above, Amselem *et al.* teaches to use α-tocopherol in combination with ***a lipid composition***. Amselem *et al.* distinguishes clearly between lipids and lipophilic substances as indicated in col. 4, l. 23-31, where the lipid compounds are responsible for increasing oral availability of the lipophilic substances. Lipophilic substances include coenzyme Q10 (see Amselem *et al.*, col. 5, l. 47-49). Thus, Amselem *et al.* teaches to use α-tocopherol to lessen oxidation of lipids and not lipophilic substances, as coenzyme Q10. More importantly, the composition disclosed in Popp *et al.* ***contains no lipids***. Thus, the skilled artisan would not be motivated to select from Amselem *et al.* a succinate for whatever reason and combine it with any embodiment from Popp *et al.* as the latter has no lipids that would benefit from Amselem *et al.*'s succinate. Thus, since the skilled person would get no suggestion to use succinate and/or fumarate from Amselem *et al.*, the skilled person would not arrive at the

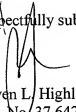
composition of the present invention. And even if these elements were disclosed by Amselem *et al.*, the skilled artisan would never have combine this reference with Popp *et al.* in the first place given the irrelevance of its teachings to the primary reference.

Consequently, applicants submit that the composition of the present invention is not obvious in view of Popp *et al.* and Amselem *et al.* Reconsideration and withdrawal of the rejection is therefore respectfully requested.

V. Conclusion

In light of the foregoing, applicant respectfully submits that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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